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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,840	04/08/2005	James B. Doherty	21260YP	9486
210 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907	7590 10/23/2008		EXAMINER ANDERSON, REBECCA L	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 10/23/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/530,840

**Applicant(s)**

DOHERTY ET AL.

**Examiner**

REBECCA L. ANDERSON

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-23 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 15 and 20-23 is/are rejected.
- 7) ☒ Claim(s) 13-15 and 20-23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 13-23 are currently pending in the instant application. Claims 13, 15 and 20-23 are rejected. Claims 13-15 and 20-23 are objected. Claims 16-19 are withdrawn from consideration as being for non-elected subject matter.

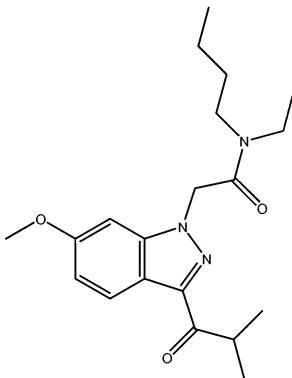
#### ***Response to Amendment and Arguments***

Applicants' amendment and remarks filed 3 July 2008 have been fully considered. While Applicants' state that the claims of the instant application are fully supported by the disclosures of the prior applications, it is noted that the newly filed claims still include, for example, R4 and R5 as SO<sub>q</sub>C1-6alkyl, COC1-6alkyl and OCF<sub>3</sub> and still include the 8<sup>th</sup> compound in Table 1, and, therefore, it is still considered that Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e).

While Applicant states that the new claims 13-23 are directed to the elected invention, it is noted that the claims still include non-elected subject matter such as when R2 and R3 are taken together with the intervening N atom to form a 4-10 membered heterocyclic carbon ring optionally interrupted. The objection to the claims as containing non-elected subject matter is therefore maintained.

Applicant argues that the provisional rejection of the claims is improper as USSN 11/630172 is not a patent and that USSN 11/630172 must always have at least one phosphate substituent attached to the molecule. These arguments are not persuasive as the reason for the rejection being a provisional rejection is that USSN 11/630172 is not yet a patent. Additionally, conflicting claim 6 claims species which anticipate

applicants' claimed invention of claims 13, 15 and 20-23, such as N-butyl-N-ethyl-2-(3-isobutyryl-6-methoxy-1H-indazol-1-yl)acetamide which corresponds to the following compound which does not include a phosphate substituent:



N-butyl-N-ethyl-2-(3-isobutyryl-6-methoxy-1H-indazol-1-yl)acetamide. The provisional rejection is therefore maintained.

### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional

application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application No. 60/424,790 and 60/500,094 fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, claims 13-23 do not find support in the prior-filed applications and the date for prior art purposes is 4 November 2003. The claims include, for example, the variables R4 and R5 to be SO<sub>q</sub>C1-6alkyl, COC1-6alkyl and OCF3 which are found nowhere in either prior filed provisional application. The claims also include, for example, the 8<sup>th</sup> listed compound in Table 1 which is found nowhere in either prior filed provisional application; the last listed compound of claim 15 on page 5 which is found nowhere in either prior filed provisional application and the compounds of Table II are not found in US Provisional Application 60/424790, nor is the last compound of Table II found in US Provisional Application 60/500094.

### ***Claim Objections***

13-15 and 20-23 are objected to as containing non-elected subject matter. Claims 13-15 and 20-23 presented drawn solely to the elected invention of Group XVIII would overcome this objection.

Claim 13 is objected to because of the following informalities: Specifically, claim 13 does not start with a capital letter. Appropriate correction is required.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13, 15 and 20-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 6 and 11-14 of copending Application No. 11/630172. Although the conflicting claims are not identical, they are not patentably distinct from each other because conflicting claims 1-3 and 5 generically overlap with applicants' claimed invention and provide preferences towards applicants' claimed compounds. Conflicting claims 11-14 are drawn to pharmaceutical compositions of claim 1 which generically overlaps with applicants' claimed invention. Additionally, conflicting claim 6 claims species which anticipate applicants' claimed invention of claims 1, 3, 4 and 9-12, such as N-butyl-N-ethyl-2-(3-isobutyl-6-methoxy-1H-indazol-1-yl)acetamide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Closest Prior Art***

The closest prior art to applicants' instant elected Group XVIII is found in US Pre-Grant Publication 20070027188, which discloses intermediate #8 on page 11 which reads on the non-elected subject matter of the application, such as wherein X is (CHR7)pCO wherein p is 1 and R7 is hydrogen; Q is O; R2 is absent; R3 is hydrogen; Y is CO(CH<sub>2</sub>)<sub>n</sub> wherein n is 0; R6 is C1-10alkyl substituted with 3 groups selected from Ra wherein Ra is F, F and C1-10 alkyl wherein said alkyl is substituted with (CH<sub>2</sub>)<sub>n</sub>OH wherein n is 0; and one of R4 and R5 is hydrogen and the other is C1-6alkoxy.

Additionally, Masaharu et al. on the 1449 submitted 27 July 2007 provides compounds which read on the non-elected subject matter of the applicaiton, such as

wherein X is (CHR7)pCO wherein p is 1 and R7 is hydrogen; Q is O; R2 is absent; R3 is hydrogen; Y is CO(CH2)n wherein n is 0; R6 is(CH2)nC6-10aryl wherein n is 0 and the aryl is substituted with one Ra group wherein Ra is Cl; and wherein one of R4 and R5 is hydrogen and the other is C1-6 alkyl (see page 2 of Masaharu et al.).

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.



The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Rebecca Anderson/  
Primary Examiner, AU 1626*

21 October 2008

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Rebecca Anderson  
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Art Unit 1626, Group 1620  
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